UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,615	07/08/2003	Clemens Hendricus, M. Kocken	2183-6041US	8276

24247 7590 01/03/2008

TRASK BRITT
P.O. BQX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
HIBBERT, CATHERINE S	
ART UNIT	**PAPER NUMBER**
1636	

NOTIFICATION DATE	DELIVERY MODE
01/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/615,615	KOCKEN ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-10,27-30,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-10,27-30,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendments to the Claims, filed 11 October 2007, have been received and entered. Claims 5-7, 11-26 and 31-45 are cancelled. Claims 1-4, 8-10, 27-30, 46 and 47 are pending and under consideration in this action.

Please note that the previous office action, mailed 10 July 2007, is considered a Non-final action (as noted on the 10 July 2007 Office Action Summary), and was not considered a final action despite the statement in the Office Action of 10 July 2007, on page 2, ¶ 2, regarding a Final action. The action is/was considered a Non-final action because some of the new grounds of rejection under the 112, second paragraph, were not necessitated by material changes to the claims but instead were directed to issues in the Claim set filed 7/10/2006 which had not been addressed in the Office Action of 2 October 2006.

Response to Arguments

Objections made in the prior Office Action to Claims 8, 27, 46 and 47 are withdrawn herein based on Applicant's Amendments to the Claims filed 11 October 2007. The objection to cancelled claim 6 is moot.

The rejection of Claims 1-4, 8-10, 27-30, 46 and 47 under ¶ 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn based on Applicant's Amendment to the Claims filed 11 October 2007. The rejection of cancelled claim 6 is moot.

New Grounds of Rejection

Claim Objections

Claims 1, 27, 46 and 47 are objected to because the phrase "amino acids residues" appears to be a typographical error for the phrase "amino acid residues". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-10, 27-30, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent Claim 1 is drawn to either a method comprising: (1) providing a yeast cell with a nucleic acid which encodes either a *Plasmodium falciparum* apical membrane antigen-1 (AMA-1) ectodomain, (wherein said ectodomain exhibits specificity for mAb 4G2), and wherein at least one glycosylation site is removed from said ectodomain, and wherein said nucleic acid comprises a nucleotide sequence of FIG. 1, and wherein said nucleic acid is modified for the yeast cell codon usage,

or a method comprising: (2) providing a yeast cell with a nucleic acid encoding a functional part of said ectodomain, (wherein said ectodomain exhibits specificity for mAb 4G2), wherein the functional part comprises the amino acid sequence "corresponding to" amino acid residues 25-442, 97-318, 97-442 or 97-545 of SEQ ID NO:6, and further to wherein the nucleic acid comprises a nucleotide sequence of FIG 1 and further to wherein said nucleic acid is modified for a yeast cell's codon usage.

A reasonable broad interpretation of the claim language in the phrase "the amino acid sequence corresponding to amino acid residues" reads on sequences which are not identical to stretches of SEQ ID NO:6 but that could be homologous or analogous to these regions of amino acid sequence. In addition, a reasonable broad interpretation of the term "comprises a nucleotide sequence of FIG 1" reads on any consecutive sequence of at least two nucleotides. In addition, the limitation of the phrase "wherein at least one glycosylation site is removed from said *Plasmodium falciparum* apical membrane antigen-1 (AMA-1) ectodomain", as written, is read as *only* limiting the AMA-1 ectodomain but not pertaining to the "functional part" of the ectodomain. In addition, the broad claim language of dependent claim 8 in the phrase "comprises mRNA encoding Plasmodium falciparum Vietnam-Oak Knoll strain ectodomain" reads broadly on any tri-nucleotide sequence encoding a single amino acid present in said Vietnam-Oak Knoll strain ectodomain. Independent claims 27, 46 and 47 are also interpreted broadly for similar reasons as given above.

More specifically the claims are directed to a genus of nucleic acid molecules that encode an AMA-1 ectodomain or a part or corresponding to a part thereof, with a

single disclosed functionality - the requirement that each molecule encodes an antigen that will produce protective immunity. (e.g. Specification, p. 5, ¶ 1; p. 12, ¶ 2; p. 14, ¶ 2; p. 15, ¶ 2; p. 16, ¶ 1). In other words, the invention is directed to a genus in terms of any nucleic acid molecule encoding any portion of any Plasmodium AMA-1 ectodomain having protective immunogenic functionality. The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

The specification does not contain a sufficient number of examples of particular embodiments for such nucleic acid molecules. The instant specification provides limited guidance for one of skill to envisage the vast number of embodiments claimed. For example, five different structures (i.e. amino acid residues 25-442, 303-442, 303-544, 419-544 and 97-545 of the sequence provided in Fig. 1) from a single species of Plasmodium *(falciparum)* are shown to react with a monoclonal antibody. (Spec. pp. 24-26). Of the five only three are shown to be reactive with the parasite-inhibitory antibody. (e.g. p. 24, bottom ¶). There is no further information provided to clarify the different regions or sequences (i.e. fragments, analogues or derivatives) that actually inhere the immunogenic functionality. Even if such clarification were provided, it would be limited

to a single species of Plasmodium, if not a single strain. (See infra, Fandeur et al. Am. J. Trop. Med. 1998; 58(2):225-31, of record). Moreover, significance of any further clarification could be host-specific. (Id.). The disclosure provides an additional two fragments (i.e. amino acid residues 97-442 and 97-318), which are shown to have some *in vitro* inhibitory activity (i.e. antibodies to said fragments result in 50-60% inhibition of invasion). However, even a single amino acid change in any of the disclosed structures could result in a distinct functionality in regard to the antigen eliciting protective immunity *in vivo,* notwithstanding *in vitro* results disclosed. In sum, the disclosure is not descriptive of the complete structure of a representative number of species, which the claims encompass, as one of ordinary skill in the art cannot envision all Plasmodium falciparum AMA-1 ectodomains, functional fragments, corresponding sequences or analogues thereof, based on the teachings in the specification.

One of skill in the art would appreciate the fact that particular Plasmodium falciparum AMA-1 ectodomains, fragments, corresponding sequences or analogues, are not necessarily interchangeable, because there can be Plasmodium variant-, strain-specific or even host specific immunity. (e.g Fandeur et al. Am. J. Trop. Med. 1998; 58(2): 225-31; e.g. Abstract; indicating Variant- and Strain-specific immunity in a simian species infected with *Plasmodium Falciparum,* of record*)*. Therefore, as amongst the broad number of embodiments of Plasmodium falciparum AMA- 1 ectodomains claimed, there would not necessarily be any functional interchangeability.

Given the enormous breadth of the nucleic acid structures encompassed by the claims, and given the limited description from the instant specification of such

structures, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus of nucleic acid molecules encoding a Plasmodium falciparum AMA-1 ectodomain, or functional part thereof comprising the amino acid sequence "corresponding to" amino acid residues 25-442, 97-318, 97-442 or 97-545 of SEQ ID NO:6. Moreover, an applicant claiming a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from other species. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the invention, as claimed.

Therefore, only specific nucleic acid sequences as described in SEQ ID NO: 6, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

Patent Examiner: Catherine S. Hibbert/AU1636